DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 7, 2015

MIPM Mammendorfer Institut fur Physik und Medizin GmbH
% Andre Kindsvater
Senior Consultant RA & QA
Emergo Europe Consulting
Prinsessegracht 20
The Hague, 2514AP NL

Re: K142032
Trade/Device Name: MRI Patient Monitoring System Tesla M3
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer and Rate Alarm)
Regulatory Class: Class II
Product Code: MWI
Dated: March 26, 2015
Received: March 26, 2015

Dear Andre Kindsvater,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

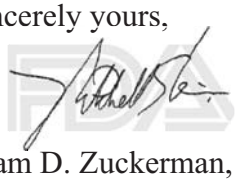
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142032

Device Name
MRI Patient Monitoring System Tesla M3

Indications for Use *(Describe)*

The MRI Patient Monitoring System Tesla M3 is intended for monitoring of vital signs during MRI examinations (MRI procedures) of patients.

The Tesla M3 is intended for use in the Adult, Pediatric and Neonatal populations for the continuous monitoring of Electrocardiogram (ECG), Non-Invasive Blood Pressure (NIBP), Invasive Blood Pressure (IBP), Temperature, Respiration, Capnography (etCO2), Oxygen and Anesthetic Agents.

The Tesla M3 is intended for use in the Adult and Pediatric populations for the continuous monitoring of Pulse Oximetry (SpO2).

The Tesla M3 is intended for use by health care professionals.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

for

MRI Patient Monitoring System Tesla M3

1. Submission Sponsor

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2. Submission Correspondent

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Contact: André Kindsvater, Senior Consultant, RA/QA
Email: project.management@emergogroup.com

3. Date Prepared

May 7th, 2015

4. Device Identification

Trade/Proprietary Name:	MRI Patient Monitoring System Tesla M3
Common/Usual Name:	Physiological Patient Monitor
Classification Name:	monitor, physiological, patient (without arrhythmia detection or alarms)
Classification Regulation:	870.2300
Product Code:	MWI
Device Class:	Class II
Classification Panel:	Cardiovascular

5. Legally Marketed Predicate Device(s)

MRI Compatible Patient Monitor Tesla Guard, 510(k) number: K071802

6. Device Description

The Tesla M3 is a MRI Patient Monitoring System that is intended to monitor and display vital signs during MRI examinations (MRI procedures) of patients. It is capable for continuous monitoring and displaying data from the following sensors/measurement modules in graphic and numeric form:

- Electrocardiogram (ECG),
- Pulse Oximetry (SpO2),
- Non-Invasive Blood Pressure (NIBP),
- Invasive Blood Pressure (IBP),
- Temperature, Respiration,
- Capnography (etCO2), and
- Oxygen and Anesthetic Agents

7. Indication for Use Statement

The MRI Patient Monitoring System Tesla M3 is intended for monitoring of vital signs during MRI examinations (MRI procedures) of patients.

The Tesla M3 is intended for use in the Adult, Pediatric and Neonatal populations for the continuous monitoring of Electrocardiogram (ECG), Non-Invasive Blood Pressure (NIBP), Invasive Blood Pressure (IBP), Temperature, Respiration, Capnography ($etCO_2$), Oxygen and Anesthetic Agents.

The Tesla M3 is intended for use in the Adult and Pediatric populations for the continuous monitoring of Pulse Oximetry (SpO_2).

The Tesla M3 is intended for use by health care professionals.

8. Substantial Equivalence Discussion

The following table compares the MRI Patient Monitoring System Tesla M3 to the predicate device with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

In the 'Significant Differences' column of the table, list the differences between the device and the predicate and briefly justify why these differences do not raise safety and effectiveness concerns.

Table 5A – Comparison of Characteristics

Manufacturer	**MIPM**	**MIPM**	**SIGNIFICANT DIFFERENCES**
Trade Name	MRI Patient Monitoring System Tesla M3	Tesla Guard	
510(k) Number	K142032	K071802	N/A
Product Code	MWI	MWI	Equivalent

Manufacturer	MIPM	MIPM	SIGNIFICANT DIFFERENCES
Trade Name	MRI Patient Monitoring System Tesla M3	Tesla Guard	
Regulation Number	870.2300	870.2300	Equivalent
Regulation Name	Monitor, Physiological, Patient (without arrhythmia detector or alarms)	Monitor, Physiological, Patient (without arrhythmia detector or alarms)	Equivalent
Indications for Use	The MRI Patient Monitoring System Tesla M3 is intended for monitoring of vital signs during MRI examinations (MRI procedures) of patients. The Tesla M3 is intended for use in the Adult, Pediatric and Neonatal populations for the continuous monitoring of Electrocardiogram (ECG), Non-Invasive Blood Pressure (NIBP), Invasive Blood Pressure (IBP), Temperature, Respiration, Capnography ($etCO_2$), Oxygen and Anesthetic Agents. The Tesla M3 is intended for use in the Adult and Pediatric populations for the continuous monitoring of Pulse Oximetry (SpO_2). The Tesla M3 is intended for use by health care professionals.	The Tesla Guard ® Patient Monitor is capable of monitoring: • SpO2 (Arterial Oxygen Saturation) • ECG (3-Lead) • IBP (Invasive Blood Pressure) • NIBP (Non-invasive Blood Pressure) • CO2 and Anesthetic Agents (with optional multi-gas module) This device will produce visual and audible alarms if any of these parameters vary beyond preset limits and produce timed or alarm recordings. With the optional multi-gas module installed, sampled breathing gases from adults and pediatrics can be displayed. The multi-gas module continuously measures the content of CO2, N2O, O2 and one of the anesthetic agents, Halothane, Isoflurane, Enflurane, Sevoflurane and Desflurane in any mixture, and communicates real time and derived gas information to the Tesla Guard ® Patient Monitor. The device is intended to be used in the environment where patient care is provided by Healthcare Professionals, i.e. physicians, nurses, and technicians, trained on the use of the device, who will determine when use of the device is indicated based upon their professional	Substantially equivalent. Tesla Guard does not have a Temperature option

Manufacturer	MIPM	MIPM	SIGNIFICANT DIFFERENCES
Trade Name	MRI Patient Monitoring System Tesla M3	Tesla Guard	
		assessment of the patient's medical condition. The device is intended for use in the Adult, Pediatric and Neonatal populations. MRI Compatibility Statement: The Tesla Guard ® Patient Monitor is designed for use in an MRI-environment at a maximum magnetic field strength of 20mT.	
Material	Housing mainly coated aluminium, antimagnetic stainless steel, plastics	Housing mainly coated aluminium, antimagnetic stainless steel, plastics	Equivalent
Latex Free	Yes	Yes	Equivalent
Sterile	No	No	Equivalent
Single-Use	No	No	Equivalent
Shelf Life	N/A	N/A	Equivalent
MRI safe	Yes	Yes	Equivalent
Overall Design	PEMS and Software	PEMS and Software	Equivalent
ECG	Waveform and Numeric	Waveform and Numeric	Equivalent
Pulse Oximetry	Waveform and Numeric	Waveform and Numeric	Equivalent
NIBP	Numeric	Numeric	Equivalent
IBP (1 or 2) (optional)	Waveform and Numeric	Waveform and Numeric	Equivalent
Capnography (optional)	Waveform and Numeric	Waveform and Numeric	Equivalent
Gases: Capnography, Oxygen and Anesthetic Agents (Auto Detection) (optional)	Waveform and Numeric	Waveform and Numeric	Equivalent
Temperature (1 or 2) (optional)	Numeric	No (the Tesla Guard does not include optional temperature measurements)	Different
Mode of operation	Continuous	Continuous	Equivalent
Battery Operated	Two batteries, Li-Ion	One battery, Pb	Equivalent
AC Powered	100 to 240 VAC, 50/60 Hz	100 to 240 VAC, 50/60 Hz	Equivalent
Complies with ISO 10993-1	Yes	Yes	Equivalent
Electrical Safety Testing Passed	Yes	Yes	Equivalent

9. Non-Clinical Performance Data

MIPM did not conduct, nor rely upon, clinical tests to determine substantial equivalence. Nonclinical testing was performed in order to validate the design against the company's

Table 5B – Performance Testing Summary

Test		Pass / fail criteria	Results
1	Electrical safety	Compliance to IEC 60601-1:2012	Passed
2	Electromagnetic compatibility	Compliance to EN/IEC 60601-1-2: 2007	Passed
3	Multifunction Patient Monitor	Compliance to IEC 60601-2-49: 2011-02	Passed
4	Alarms	Compliance to IEC 60601-1-8:2006+A1:2012-11	Passed
	Biocompatibility	Compliance to ISO 10993-1	Passed
	Risk Management	Compliance to ISO 14971:2007	Passed
5	Software	Compliance to IEC 62304:2006	Passed
6	Pulse Oximeter	Compliance to ISO 80601-2-61: 2011	Passed
7	Respiratory Gas Monitor	Compliance to ISO 80601-2-55: 2011-12	Passed
8	IBP	Compliance to IEC 60601-2-34:2011-05	Passed
9	NIBP	Compliance to IEC 80601-2-30:2009-01 (ed.1.0)	Passed
10	ECG	Compliance to IEC 60601-2-27:2011-03 (ed.3.0)	Passed
11	Thermometers	Compliance to ISO 80601-2-56: 2009 (ed. 1.0)	Passed

For a complete listing of all applicable performance standards and their extent of compliance see Section 09 - Declarations of Conformity and the corresponding Summary Reports.

10. Clinical Performance Data

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. These types of devices, including the predicate devices, have been on the market for many years with a proven safety and efficacy for the use of the device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

11. Statement of Substantial Equivalence

It has been shown in this 510(k) submission that the difference between the Tesla M3 and the predicate devices do not raise any questions regarding its safety and effectiveness. The Tesla M3, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate device.